DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

MY1150

WARNING LETTER
VIA FEDERAL EXPRESS

AUG 28 2000

Mr. Chau-Luh Hu
Factory Manager
Taiwan Fuji Latex Company, Ltd.
46-3, Pi Dao Li
Tamshui, Taipei Hsien 251
Taiwan

Dear Mr. Hu:

During the Food and Drug Administration (FDA) inspection of your facility located in Tamshui, Taiwan, conducted on June 12-13, 2000, the FDA investigator determined that your firm manufactures condoms. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated under Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Failure to document validation activities and results for processes which cannot be fully verified by inspection and test as required by 21 CFR 820.75(a). For example:

(a) There has been no formal validation of the [redacted] testing process at the Tamshui plant. Such a validation would require a study comparing the results of [redacted] with the results of [redacted] testing for different values of the [redacted] test parameters [redacted] We note that your firm does perform "manual" condom testing to confirm proper operation of the [redacted] each hour using an alternate [redacted] test commonly used in Japan. However, this challenge testing only "verifies" the existing settings and does not optimize the [redacted] method. Furthermore, the value of the challenge test method is questionable unless it too has been validated to a [redacted] test method that is contained in recognized consensus standards such as the ISO or ASTM condom standards. After the optimum [redacted] test settings have been determined by the study, consistency of the [redacted] process should be demonstrated by a minimum of three consecutive production lots which are successfully tested at the optimum settings.

(b) There has been no formal validation of the [redacted] detection alarm. Your firm does perform daily challenge testing, however, as discussed above, this is not a substitute for validation.

2. Failure to control production processes to ensure that a device conforms to its specifications as required by 21 CFR 82.70(a). For example, the investigator observed that when he reviewed the device history records for two dates, June 13 and May 29, 2000, these records indicated that the [redacted] temperature for the [redacted] test was outside of the specified range. The investigator also observed that your firm does not document such occurrences in the corrective and preventive action program.

In addition to the above noted issues relating to the Quality Systems Regulation, the investigator noted that your firm does not have data from long term (90 day) accelerated aging, or from real-time stability testing of its condoms to verify the claimed five-year shelf life. Pursuant to 21 CFR 801.435 effective March 25, 1998 (copy enclosed), such data must be developed and must be maintained on file for FDA inspection. Please note that these stability studies must be based on condoms that are left unpackaged for the maximum time prior to packaging as described in 21 CFR 801.435(d)(3).

Until such real-time testing studies are initiated, your condoms will be considered misbranded under Section 502(f)(1) of the Act in that its label fails to provide adequate direction for use and may be refused entry. Please provide us with a copy of your proposed study protocol including the condom types, the claimed shelf life you intend to verify, maximum elapsed time between dipping and packaging, types of tests to be conducted to verify continued quality over the claimed shelf life, sample sizes, time intervals between tests, acceptance criteria and other relevant factors.

Finally, the investigator noted that your firm's latex condoms lack the latex "Caution" statement required by 21 CFR 801.437(d) ["Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions"]. This statement is required on all medical devices containing latex distributed in the United States after September 30, 1998.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

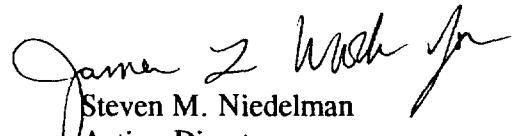
Given the serious nature of these violations of the Act, all devices manufactured by Taiwan Fuji Latex Co., Ltd. at Tamshui, Taiwan, may be detained upon entry into the United States without physical examination until these violations are corrected.

In order to remove the devices from detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that your response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections has been verified, your products may resume entry into this country.

We note that your firm has never responded to our previous Warning Letter dated February 25, 1999, and that the investigator determined that your firm has not distributed products in the United States since 1993. When your firm has decided that it intends to resume exporting to the United States, please notify this office in writing regarding the specific steps you have taken, or intend to take, to correct the noted violations, including an explanation of each step being taken to identify and make necessary corrections to any underlying systems problems to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If the documentation is not in English, please provide an English translation to facilitate our review. Please send your response and any questions to Mr. Paul F. Tilton, Acting Chief, OB/GYN, Gastroenterology, & Urology Branch, at the letterhead address.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Mr. John Farnham at the letterhead address, at (301) 594-4616 or FAX (301) 594-4638.

Sincerely yours,



Steven M. Niedelman
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure